


## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 1843.020PC01	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US03/30238	International filing date (day/month/year) 26 September 2003 (26.09.2003)	Priority date (day/month/year) 27 September 2002 (27.09.2002)
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 39/00, 39/385, 39/44 and US Cl.: 530/350, 402; 424/185.1, 178.1, 193.1		
Applicant VACCINEX, INC.		
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 4 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of ___ sheets.</p> <p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input checked="" type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>		
Date of submission of the demand 27 April 2004 (27.04.2004)	Date of completion of this report 11 April 2005 (11.04.2005)	
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/ US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer  Marianne DiBrino, Ph.D. Telephone No. 571-272-1600	

**I. Basis of the report****1. With regard to the elements of the international application:\***

- ☒ the international application as originally filed.
- ☒ the description:  
pages 1-107 as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_.
- ☒ the claims:  
pages 108-113, as originally filed  
pages NONE, as amended (together with any statement) under Article 19  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_.
- ☒ the drawings:  
pages 1-3, as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_.
- ☒ the sequence listing part of the description:  
pages 1-34, as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_.

**2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.**

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

**3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing**

- ☒ contained in the international application in printed form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

**4. ☐ The amendments have resulted in the cancellation of:**

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

**5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\***

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

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**III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The question whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

- ☐ the entire international application,  
☒ claims Nos. Claims 10-48 were not examined because they were not searched in Chapter 1.

because:

- ☐ the said international application, or the said claim Nos. \_\_\_\_\_ relate to the following subject matter which does not require international preliminary examination (*specify*):

- ☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 10-48 are so unclear that no meaningful opinion could be formed (*specify*):

Claims 10-48 because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

- ☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported by the description that no meaningful opinion could be formed.  
☐ no international search report has been established for said claims Nos. \_\_\_\_\_

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

- ☐ the written form has not been furnished or does not comply with the standard.  
☐ the computer readable form has not been furnished or does not comply with the standard.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.  
PCT/US03/30238**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. STATEMENT**

Novelty (N)	Claims <u>1-9</u>	YES
	Claims <u>NONE</u>	NO
Inventive Step (IS)	Claims <u>5 and 6</u>	YES
	Claims <u>1-4 and 7-9</u>	NO
Industrial Applicability (IA)	Claims <u>1-9</u>	YES
	Claims <u>NONE</u>	NO

**2. CITATIONS AND EXPLANATIONS**

Claims 1-4 and 7-9 lack an inventive step under PCT Article 33(3) as being obvious over obvious in view of US 2002/0071842 A1 in view of WO 01/78768 A2.

US 2002/0071842 A1 discloses CD1d-IgG multimers further comprising lipid or glycolipid antigen for use in targeting T cells. US 2002/0071842 A1 discloses that an antigen for CD1d is a-GalCer, and that CD1d/antigen complexes are recognized by T cells. US 2002/0071842 A1 discloses multimerizing CD1d/antigen/IgG using avidin/biotin. US 2002/0071842 A1 discloses using the multimers in vaccine formulations to treat autoimmunity, cancer or infectious diseases.

US 2002/0071842 A1 does not disclose wherein the antibody or fragment thereof is specific for a cell surface marker, nor wherein the antibody is a F(ab) or an F(ab')<sub>2</sub> or a full-length antibody.

WO 01/78768 A2 teaches a targeted vaccine delivery system comprising one or more MHC/peptide antigen complexes (recognized by T cells) linked to an antibody which is specific for a cell surface marker such as a T cell surface marker, and use in treating cancer, infectious disease, autoimmune disease and/or allergies. WO 01/78768 A2 further teaches F(ab), full length antibodies or F(ab')<sub>2</sub> (especially Abstract and page 24).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have used an antibody to a T cell surface marker as taught by WO 01/78768 A2 for MHC/peptide/antibody or fragment thereof multimeric complexes in the complexes disclosed by US 2002/0071842 A1 for CD1d/lipid antigen/IgG multimeric complexes.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this in order to more effectively target CD1d/peptide complexes to T cells since US 2002/0071842 A1 teaches targeting T cells and WO 01/78768 A2 teaches using antibodies or fragments thereof to target another complex recognized by T cells, i.e., MHC/peptide complexes, to T cells or other cells such as tumor targets.

Claims 5 and 6 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest modified a-GalCer antigens recited in the said claims.

Claims 1-9 meet the criteria set out in PCT Article 33(4), and thus meet industrial applicability because the subject matter claimed can be made or used in industry.